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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 41914.465

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Application Number	Filed
10/617,895	July 11, 2003

First Named Inventor: Ryan P. Boucher

Art Unit	Examiner
3734	Diane D. Yabut

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 28,867.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

J. Richard Konneker
Signature

J. Richard Konneker
Typed or printed name

972-739-8612
Telephone number

NOVEMBER 12, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☑ *Total of one forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ryan P. Boucher et al.	§	Attorney Docket No.: P0031798.155 | 41914.465
	§	
	§	Customer No.: 46333
Application No.: 10/617,895	§	
	§	Group Art Unit: 3734
Filed: July 11, 2003	§	
	§	Examiner: Yabut, Diane D.
For: Expandable Preformed Structures for Deployment in Interior Body Regions	§	
	§	Confirmation No.: 4066

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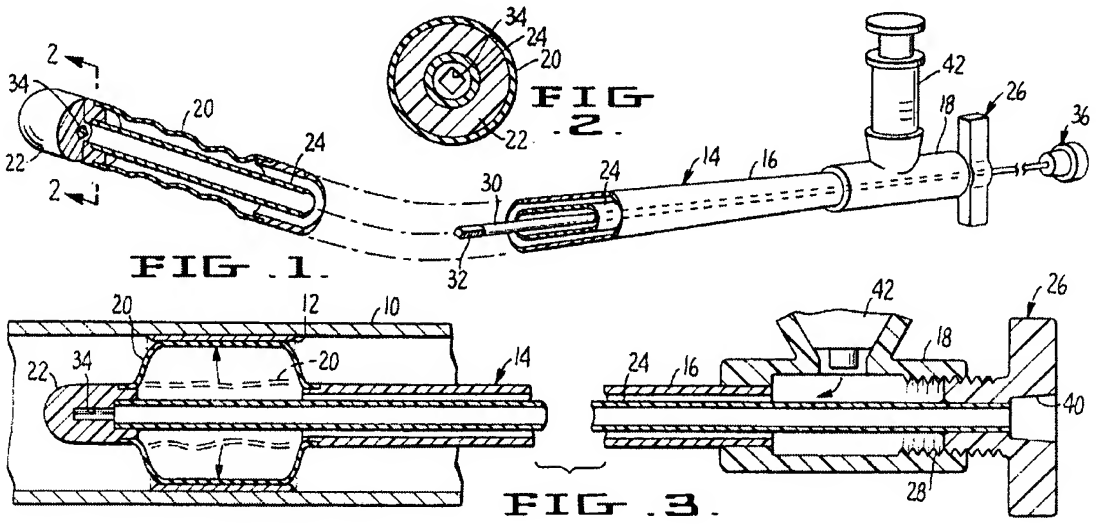
REMARKS ACCOMPANYING PRE-APPEAL BRIEF REQUEST FOR REVIEW

Please consider the following remarks in support of the concurrently filed Pre-Appeal Brief Request for Review.

A. Rejection of Claims 1-5, 7-9, and 12-15 Based On Fogarty and Moutafis

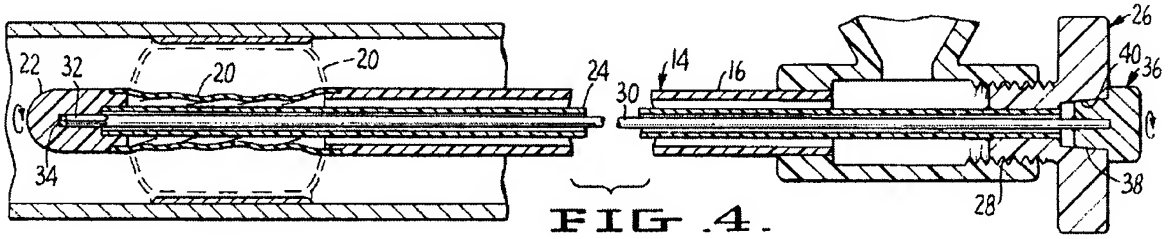
Applicants submit that there is clear error with respect to the rejection of claims 1-5, 7-9, and 12-15 under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 4,483,340 to Fogarty et al. ("Fogarty") in view of U.S. Patent No. 5,090,957 to Moutafis et al. ("Moutafis"). Applicants submit that the rejection of claim 1 is clear error because even when combined, Fogarty and Moutafis do not disclose or suggest a tool having "a catheter body defining an interior lumen and having a distal end opening through which a substance may be flowed outwardly from the interior lumen into an interior body region, . . . the distal end opening of the catheter body being configured to prevent outward movement of the stylet therethrough," and the "stylet having a proximal end and being sized and configured for passage through the interior lumen and adapted to straighten the expandable structure during deployment into an interior body region, the stylet being selectively insertable into and withdrawable from an interior of the expandable structure via the interior lumen," as recited by independent claim 1.

Referring to Figs. 1-3 reproduced below from Fogarty, the Final Office Action identified inner tube 24, socket 34, and core wire 30 as corresponding to the claimed catheter, distal end opening of the catheter, and the stylet, respectively.



As clearly shown above, inner tube 24 terminates at tip member 22. In other words, a distal end opening of inner tube 24 is located at the interface between the inner tube 24 and tip member 22. However, as shown above, socket 34 is located within tip member 22. Thus, socket 34 cannot be considered the distal end opening of inner tube 24.

Moreover, as shown below in Fig. 4, end 32 of core wire 30 is allowed to extend past the distal end of inner tube 24.



Thus, inner tube 24 does not have a distal opening configured to prevent outward movement of core wire 30 as recited by claim 1. Still further, the Examiner even admits that "Fogarty et al do not disclose the distal end opening through which a substance may be flowed outwardly from the interior lumen into an interior body portion," as recited by claim 1. Final Office Action, p.4.

The Moutafis reference does not cure these deficiencies. Referring to Fig. 3B below, the Final Office Action identified nosepiece 230 and either inner tube 214 or insert 240 as corresponding to claimed distal end of the catheter and stylet, respectively.

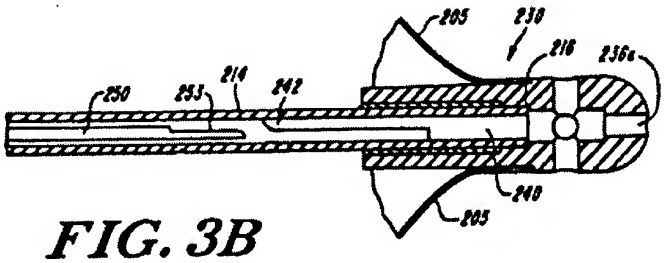


FIG. 3B

Applicants respectfully disagree. First, neither inner tube 214 nor insert 240 is a **stylet** as the Examiner contends. In ordinary and customary medical parlance, the accepted meaning of the term "stylet" is "a wire run through a catheter or cannula to render it stiff or to remove debris from its lumen", and the accepted meaning of the term "catheter" is "a hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway." Moutafis does not disclose that inner tube 214 or insert 240 has these features.

Moreover, Moutafis states that "inner tube 214 butts against an end wall 216 and is **permanently cemented thereto**." Moutafis, col.3 ll.64-65 (emphasis added). Additionally, Moutafis states that "insert 240 also abuts wall 216 and is **press-fit to provide rigid engagement** with tube 214 and nosepiece 230." Moutafis, col.3 ll.66-68 (emphasis added). However, claims 1 recites that "the stylet [is] selectively **insertable into and withdrawable from** an interior of the expandable structure via the interior lumen." Non-moveable components such as inner tube 214 and insert 240 do not disclose or suggest these features of claim 1.

Furthermore, even if insert 240 were to be characterized as a "stylet", it is disclosed in the Moutafis specification (beginning on line 1 of column 4) that the outer tube diameter of insert 240 is **matched to the inner diameter of the tube 214**. It thus appears in FIG. 3B that the outer diameter of the insert 240 is sufficiently small to permit the member 240 to pass distally outwardly through the opening 236a. **The Moutafis et al distal end opening 236a accordingly does not appear to be configured to prevent movement of the tubular member 240 outwardly therethrough as contended by the Examiner**.

For at least the foregoing reasons it is respectfully submitted that none of applicants' Claims 1-5 is rendered obvious by the Fogarty et al/Moutafis et al reference combination being proposed by the Examiner. Therefore, the rejection of claims 1-5 based on Fogarty and Moutafis is clear error.

Independent claim 7 recites at least some features similar to those of claim 1. Claims 8, 9, and 12-15 depend from and add additional features to claim 7. These claims are believed to be allowable over the cited references for at least the same reasons as discussed above with respect to claim 1. Therefore, the rejection of claims 7-9 and 12-15 based on Fogarty and Moutafis is clear error.

B. Rejection of Claims 7 and 10 based on Vargas, Fogarty, and Moutafis

Applicants submit that there is clear error with respect to the rejection of claims 7 and 10 under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,468,245 to Vargas, III ("Vargas") in view of Fogarty and Moutafis. Applicants submit that the rejection of claim 1 is clear error because even when combined, Fogarty and Moutafis do not disclose or suggest a tool having "a catheter tube assembly including . . . [an] inner elongated body having an open distal end configured to prevent movement of the stylet outwardly therethrough, the open distal end being in communication with the inner body lumen such that a substance introduced into a proximal opening of the inner body passes through the inner body lumen and is discharged from the tool through the distal opening of the inner body," and a "stylet being selectively insertable into and withdrawable from a lumen of the expandable structure via the inner body lumen."

As discussed above with respect to claim 1, neither Fogarty nor Moutafis teaches or suggests these features. Furthermore, the Examiner acknowledges that:

> Vargas, III lacks a stylet having a proximal end and being sized and shaped for passage through the inner body lumen and adapted to straighten the expandable structure during deployment and the inner body having an open distal end allowing introduction of a substance therethrough while preventing movement of the stylet outwardly therethrough.

Final Office Action, p.5. Thus, it is thus respectfully submitted that neither of applicants' claims 7 and 10 is rendered obvious by the combination of Vargas, Fogarty, and Moutafis. Therefore, the rejection of claims 7 and 10 based on Vargas, Fogarty, and Moutafis is clear error.

C. Rejection of Claims 16-18 and 20 based on Vargas and Fogarty

Applicants submit that there is clear error with respect to the rejection of independent claim 16 under 35 U.S.C. §103 as being unpatentable over Vargas in view of Fogarty. Specifically, Vargas and Fogarty, even when combined do not disclose or suggest a tool having an "expandable structure comprising a **first segment expandable to a generally spherical shape** and forming a first cavity, a **second segment expandable to a generally spherical shape** and forming a second cavity, and a joining section disposed between and interconnecting the first and second segments, the first expandable segment having a first expansion radius and the second expandable segment having a second expansion radius."

Referring to Figs. 10 and 22 reproduced below from Vargas, the Examiner alleges that balloon 1 discloses these features of claim 16.

FIG. 22

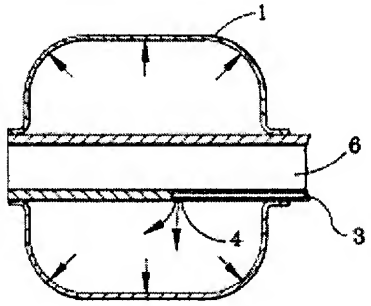
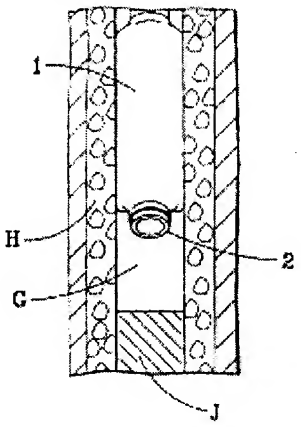


FIG. 10



However, it can clearly be seen that the inflated configuration of the balloon 1 in Fig. 10 is substantially cylindrical or square shaped and balloon 1 in Fig. 22 is substantially **cylindrical**. Furthermore, balloon 1 in either figure **does not comprise first and second generally spherical** segments interconnected by a joining section as recited in claim 16.

These expandable structure shape deficiencies are in no manner cured by Fogarty. As may be readily seen in Fig. 3 above of Fogarty, balloon element 20 is shown having a generally **cylindrical** inflated shape.

For at least these reasons it is respectfully submitted that none of applicants' claims 16-18 and 20 is rendered obvious by the Vargas,/Fogarty reference combination proposed by the Examiner.

D. Conclusion

In view of the foregoing remarks, it is respectfully submitted that there is clear error with respect to the pending claims. Accordingly, Applicants respectfully submit that this claim is in condition for allowance.

Respectfully submitted,

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I hereby certify that this correspondence is being filed with the U.S. Patent and Trademark Office via EFS-Web on 12 November 2010

Saadia Cooks